



ATTORNEY DOCKET NO. 15113.0005U2  
PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of	)	
	)	
Jeffrey L.C. Wright <i>et al.</i>	)	Art Unit: 1621
	)	
Application No. 10/070,181	)	Examiner: Karl J. Puttlitz
	)	
Filing Date: July 8, 2002	)	Confirmation No. 3116
	)	
For: NUTRITIONAL SUPPLEMENT FOR	)	
LOWERING SERUM TRIGLYCERIDE	)	
AND CHOLESTEROL LEVELS	)	

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

NEEDLE & ROSENBERG, P.C.  
Customer Number 23859

Sir:

Pursuant to the requirements of 37 C.F.R. § 1.56, submitted herewith on the accompanying Information Disclosure Statement List is a listing of documents known to Applicants and/or their attorneys. All of the documents cited were cited by or submitted to the Patent Office in Application No. 09/385,834, filed August 30, 1999, to which the present application claims priority. Pursuant to 37 C.F.R. § 1.98(d), copies of these documents are not enclosed.

In accordance with the provisions of M.P.E.P. § 2001.06(b) and 37 C.F.R. § 1.98(b)(3), Applicants would like to bring to the attention of the Examiner the existence of the co-pending

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patent application(s) identified below, which were filed in the United States Patent and

Trademark Office:

	<u><b>Application No.</b></u>	<u><b>Date Filed</b></u>	<u><b>Inventors</b></u>	<u><b>Attorney Docket No.</b></u>
1.	09/385,834	August 30, 1999	Jeffrey Wright <i>et al.</i>	15113.0005U1

In accordance with the requirements of 37 C.F.R. § 1.98(a)(2)(iii), a copy of the above-referenced application specification(s), including the claims and drawings thereof, is enclosed.

Below is a list of actions issued and responses made thereto in connection with U.S. Application No. 09/385,834. Copies of the actions and responses which are available to the undersigned are attached hereto.

	<b>Date of Action</b>	<b>Type of Action</b>	<b>Date of Response</b>
1.	06/05/2000	Restriction Requirement	06/16/2000
2.	08/14/2000	Non-Final Office Action	11/10/2000
3.	02/13/2001	Final Office Action	04/12/2001
4.	05/02/2001	Advisory Action	06/04/2001
5.	07/03/2001	Non-Final Office Action	10/03/2001
6.	12/17/2001	Final Office Action	04/15/2002
7.	04/26/2002	Non-Final Office Action and Interview Summary of August 1, 2002	07/15/2002
8.	10/21/2002	Non-Final Office Action	a
9.	11/26/2002	Non-Final Office Action	04/18/2003
10.	07/16/2003	Final Office Action	02/13/2004
11.	06/29/2004	Non-Final Office Action	b
12.	10/01/2004	Non-Final Office Action	c

a Applicants requested a supplemental Office Action from the Examiner during an interview dated October 30, 2002, which is the non-final Office Action dated November 26, 2002. A response to the supplemental Office Action was filed on April 18, 2003.

b Due to errors in the Office Action dated June 29, 2004, this Office Action was withdrawn and a new Office Action was issued on October 1, 2004.

c. A response will be filed and submitted in a supplemental Information Disclosure Statement.

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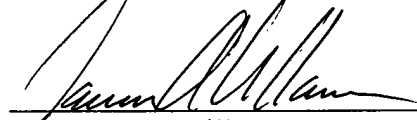
This Information Disclosure Statement is believed to be filed in a timely manner pursuant to 37 C.F.R. § 1.97(c), in that neither a final Office Action nor a Notice of Allowance has been mailed to Applicants. Accordingly, Applicants enclose the fee required under 37 C.F.R. § 1.97(c)(2).

Consideration of the cited documents and making the same of record in the prosecution of the above-referenced application are respectfully requested.

A Credit Card Payment Form PTO-2038 to cover the fee under 37 C.F.R. § 1.17(p) is enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.



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**CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8**

I hereby certify that this correspondence, including any items indicated as attached or included, is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-145, on the date indicated below.

  
Lawrence A. Villanueva, Ph.D.

Date

2/28/05

**INFORMATION DISCLOSURE  
STATEMENT LIST**

MAR 02 2005

(Use as many sheets as necessary)

Complete if Known

Application Number	10/070,181
Filing Date	July 8, 2002
First Named Inventor	Wright <i>et al.</i>
Group Art Unit	1621
Examiner Name	Karl J. Puttlitz

**U.S. PATENT DOCUMENTS**

Examiner's Initials	Cite No.	Document No.	Date	Name	Class	Subclass	Filing Date (if appropriate)
	D1	6,589,588	07/2003	Wester <i>et al.</i>	426	607	
	D2	6,162,483	12/2000	Wester	426	607	
	D3	5,965,449	10/1999	Novak	436	71	
	D4	5,892,068	06/1999	Higgins	552	554	
	D5	5,604,216	02/1997	Horrobin	514	182	
	D6	5,502,045	03/1996	Miettinen <i>et al.</i>	514	182	
	D7	4,681,896	07/1987	Horrobin	514	552	
	D8	4,526,902	07/1985	Rubin	514	560	
	D9	2004/0062847	04/2004	Koike <i>et al.</i>	426	601	
	D10	2004/0052920	03/2004	Koike	426	601	
	D11	2003/0198727	10/2003	Koike <i>et al.</i>	426	601	
	D12	2003/0054082	03/2003	Koike <i>et al.</i>	426	601	
	D13	2002/0160990	10/2002	Burdick <i>et al.</i>	514	182	
	D14	2002/0055493	05/2002	Burdick <i>et al.</i>	514	169	
	D15	2002/0016314	02/2002	Schersl	514	169	

**FOREIGN PATENT DOCUMENTS**

Examiner's Initials	Cite No.	Foreign Patent Document Country Code-Number-Kind Code	Date	Name	Translation Yes/No
	D16	CA 1337548	11/1995		
	D17	EP 0 594 612 B1	05/1991		
	D18	EP 9 703 329	02/1997		
	D19	WO 92/19640	11/1992		
	D20	WO 96/10033	04/1996		
	D21	WO 96/38047 A1	12/1996		
	D22	WO 97/35594	10/1997		
	D23	WO 98/01759	01/1998		
	D24	WO 98/06714	02/1998		
	D25	WO 98/18429	05/1998		
	D26	WO 99/30569	06/1999		

**NON-PATENT DOCUMENTS**

Examiner's Initials	Cite No.	Non-Patent Citations (include Author, Title, Publisher, Relevant Pages, Date and Place of Publication)
	D27	"Dietary Supplementation with n-3 Polyunsaturated Fatty Acids and Vitamin E after Myocardial Infarction: Results of the GISSI-Prevention Trial," <i>The Lancet</i> , 354:447-455 (1999)
	D28	"Randomised Trial of Cholesterol Lowering in 4444 Patients with Coronary Heart Disease: The Scandinavian Simvastatin Survival Study (4S)," <i>The Lancet</i> Vol. 344, Nov. 19, 1383-1389 (1994)
	D29	Burr, M.L. <i>et al.</i> , "Effects of Changes in Fat, Fish, and Fibre Intakes on Death and Myocardial Reinfarction: Diet and Reinfarction Trial (Dart)," <i>The Lancet</i> , 757-761 (1989)
	D30	Carey, Martin C. <i>et al.</i> , "Lipid Digestion and Absorption," <i>Ann. Rev. Physiol.</i> 45:651-77 (1983)
	D31	Connor, Sonja L. <i>et al.</i> , "Are Fish Oils Beneficial in the Prevention and Treatment of Coronary Artery Disease?" <i>Am. J. Clin. Nutr.</i> 66 (Suppl.): 1020S-31S (1997)
	D32	Criqui, M.H., "Triglycerides and Cardiovascular Disease, A Focus on Clinical Trials," <i>European Heart Journal</i> 19 (Supplement A): A36-A39
	D33	Eisenberg, Daniel, "The Importance of Lowering Cholesterol in Patients with Coronary Heart Disease," <i>Clin. Cardiol.</i> 21:81-84 (1998)

Examiner Signature:

Date Considered:

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Complete if Known

Application Number	10/070,181
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INFORMATION DISCLOSURE STATEMENT LIST		Filing Date	July 8, 2002
		First Named Inventor	Jeffrey Wright
		Group Art Unit	1621
		Examiner Name	Karl J. Puttlitz
(Use as many sheets as necessary)			
NON-PATENT DOCUMENTS			
Examiner's Initials	Cite No.	Non-Patent Citations (include Author, Title, Publisher, Relevant Pages, Date and Place of Publication)	
	D34	Franceschini, G. <i>et al</i> , "Pharmacological Control of Hypertriglyceridemia," (1993) <i>Cardiovas. Drugs Ther.</i> , 7, 297-302	
	D35	Gotto, Antonio M., Jr., "Triglyceride, The Forgotten Risk Factor," <i>Circulation</i> , 97: 1027-1028 (1998)	
	D36	Grundty, Scott M., "Hypertiglyceridemia, Atherogenic Dyslipidemia, and the Metabolic Syndrome," <i>American Journal of Cardiology</i> , 81 (4A): 18B-25B (1998)	
	D37	Grundty, Scott M., "Small LDL, Atherogenic Dyslipidemia, and the Metabolic Syndrome," <i>Circulation</i> 95:1-4 (1997)	
	D38	Guido Franceschini and Rodolfo Paoletti, "Pharmacological Control of Hypertriglyceridemia," <i>Cardiovascular Drugs and Therapy</i> , 1993:7:297-302 (1993)	
	D39	Harris, William S., "Fish Oils and Plasma Lipid and Lipoprotein Metabolism in Humans: A Critical Review," <i>Journal of Lipid Research</i> , 30:785-807 (1989)	
	D40	Heinemann T. <i>et al.</i> , "Effect of Low-Dose Sitostanol on Serum Cholesterol in Patients with Hypercholesterolemia," <i>Artherosclerosis</i> 61:219-223 (1986)	
	D41	Heinemann, T. <i>et al.</i> , "Mechanisms of Action of Plant Sterols on Inhibition of Cholesterol Absorption, Comparison of Sitosterol and Sitostanol," <i>European Clinical Pharmacology</i> , Vol. 40: Suppl. 1: S59-S63 (1991)	
	D42	Jeppesen, Jorgen <i>et al.</i> , "Triglyceride Concentration and Ischemic Heart Disease, An Eight-Year Follow-up in the Copenhagen Male Study," <i>Circulation</i> 97:1029-1036 (1998)	
	D43	Jones, Peter <i>et al.</i> , "Dietary Phytosterols as Cholesterol-Lowering Agents in Humans," <i>Can. J. Physiol. Pharmacol.</i> 75:217-227 (1997)	
	D44	Kinsella, John E. <i>et al.</i> , "Dietary n-3 Polyunsaturated Fatty Acids and Amelioration of Cardiovascular Disease: Possible Mechanisms <sup>1-3</sup> ," <i>Am. J. Clin. Nutr.</i> , 52:1-28 (1990)	
	D45	Leaf, Alexander <i>et al.</i> , "Medical Progress, Cardiovascular Effects of n-3 Fatty Acids," <i>The New England Journal of Medicine</i> , No. 9, 318:549-557 (1988)	
	D46	Ling, W.H. <i>et al.</i> , "Dietary Phytosterols: A Review of Metabolism, Benefits and Side Effects," <i>Life Sciences</i> Vol. 57, No. 3: 195-296 (1995)	
	D47	Miettinen, Tatu <i>et al.</i> , "Regulation of Cholesterol Metabolism by Dietary Plant Sterols," <i>Current Opinion in Lipidology</i> , 10:9-14 (1999)	
	D48	Mishkel, Gregory J. <i>et al.</i> , "Cardiovascular Effects of $\omega$ -3 Polyunsaturated Fatty Acids (Fish Oils)," <i>Bailliere's Clinical Haematology</i> , No. 3, 3:625-649 (1990)	
	D49	Sacks, Frank M. <i>et al.</i> , "The Effect of Pravastatin on Coronary Events After Myocardial Infarction in Patients with Average Cholesterol Levels," <i>The New England Journal of Medicine</i> , Vol. 335: 1001-9 (1996)	
	D50	Shimada <i>et al.</i> , "Enzymatic Synthesis of Steryl Esters of Polyunsaturated Fatty Acids," <i>J. American Oil Chemists</i> , Vol. 76, No. 6, June 1999 pp. 713-716	
	D51	Shepherd, James <i>et al.</i> , "Prevention of Coronary Heart Disease with Pravastatin in Men with Hypercholesterolemia," <i>The New England Journal of Medicine</i> , Vol. 333, 1301-1307 (1995)	
	D52	Vanhanen, H.T. <i>et al.</i> , "Serum Levels, Absorption Efficiency, Faecal Elimination and Synthesis of Cholesterol During Increasing Doses of Dietary Sitostanol Esters in Hypercholesterolaemic Subjects," <i>Clinical Science</i> , 87:61-67 (1994)	
	D53	Vanhanen, Hannu T. <i>et al.</i> , "Serum Cholesterol, Cholesterol Precursors, and Plant Sterols in Hypercholesterolemic Subjects with Different apoE Phenotypes During Dietary Sitostanol Ester Treatment," <i>Journal of Lipid Research</i> , 34:1535-1544 (1993)	
	D54	von Shacky, Clemens <i>et al.</i> , "The Effect of Dietary $\omega$ -3 Fatty Acids on Coronary Atherosclerosis, A Randomized, Double-Blind, Placebo-Controlled Trial," <i>Annals of Internal Medicine</i> , 130:554-562 (1999)	
Examiner Signature:		Date Considered:	
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			